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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,047	12/15/2003	Jacob A. Flagle	8627/44	4057

7590 09/28/2006

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,047

Applicant(s)

FLAGLE ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/16/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/1/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/16/06 has been entered.

Information Disclosure Statement

The information disclosure statement filed 9/1/06 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 14 – 16, 19, 20 and 26 - 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,345,602 to Yoshimura et al.

In regards to claims 14 – 16, 19, 20 and 26 – 28, Yoshimura et al. discloses an elongate member having a proximal end, a main body having a first diameter (Col. 4, lines 47 – 50), a distal

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end comprising an elongate tip having a first length and a second diameter, and a taper portion disposed directly between the main body and the distal end and defining a first taper between the first and second diameters (Figure 1A); a coating disposed on the distal end, the coating having a second taper that approximates the first taper of the taper portion and comprising a flexible tip (2, 6) having a second length axially extending beyond the elongate tip, the second length being equal to or greater than the first length, the coating having an outer diameter approximately equal to or less than the first diameter of the main body (Col. 3, lines 13 – 14). The flexible tip includes a solid radiopaque marker disposed therein supported solely by the coating (Col. 2, lines 67 – Col. 3, line 3; Col. 4, lines 36 – 43). The coating is disposed on at least a portion of the taper portion. The flexible tip has a rounded tip and is capable of acquiring a J-shape.

4. Claims 1 and 4 - 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,340,441 to Meyer et al.

In regards to claims 1 and 4 – 10, Meyer et al. discloses an elongate member (Figure 1) having a proximal end (12), a main body having a first diameter (Col. 3, lines 20 – 22), a distal end comprising an elongate tip (14) having a second substantially uniform diameter, and a taper portion (20) disposed directly between the main body and a distal end and defining a first taper between the first and second diameters (Col. 3, lines 43 – 47); and a coating (32, 34) having a second taper that approximates the first taper disposed on the distal end and comprising a flexible tip having a length axially extending beyond the distal end, the ratio of the length to the first diameter being greater than 3:1 (Col. 4, lines 5 – 8), the coating having a proximal portion and a distal portion, the proximal portion commencing within the taper portion of the elongate member (Col. 3, lines 48 – 51). Meyer et al. discloses the length of the flexible tip being greater than 3mm (Col. 4, lines 5 – 8). The coating comprises an outer diameter approximately equal to or less than the first diameter (Col. 4, lines 9 –

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14). The elongate member is either stainless steel or nitinol (Col. 3, lines 30 – 33). A lubricious coating is disposed on a portion of the main body (Col. 4, lines 33 – 35). Meyer et al. discloses the flexible tip comprising opacifying agent and varying the concentration of the opacifying agent (Col. 3, lines 56 – 62).

5. Claims 1 – 28 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application No. 2004/0087876 to Eskuri.

In regards to claims 1 – 28, Eskuri discloses an elongate member (Figure 1) having a proximal end (20), a main body having a first diameter, a distal end comprising an elongate tip (22) having a second substantially uniform diameter, and a taper portion disposed directly between the main body and a distal end and defining a first taper between the first and second diameters [0017] [0018]; and a coating [0022] – [0024] having a second taper that approximates the first taper disposed on the distal end and comprising a flexible tip having a length axially extending beyond the distal end, the ratio of the length to the first diameter being greater than 3:1 and between 12:1 and 250:1 [0018][0028][0029], the coating having a proximal portion and a distal portion, the proximal portion commencing within the taper portion of the elongate member (Figure 1). The coating is a blend of polymers [0024]. Eskuri discloses the length of the flexible tip being greater than 3mm [0028][0029]. The length of the flexible tip extending beyond the distal tip is greater than the length of the distal tip [0020][0028][0029]. The elongate member is either stainless steel or nitinol [0016]. A lubricious coating is disposed on a portion of the main body [0030]. The flexible tip comprises radiopaque material [0026]. A solid marker is disposed in the flexible tip and a portion of the coating is disposed between the distal end of the elongate member [0026] and provides localized weight to the flexible tip. The flexible tip comprises a curvilinear distal portion [0023]. The flexible tip includes an opacifying agent [0026].

Response to Arguments

6. Applicant's arguments filed 8/16/06 have been fully considered but they are not persuasive. Applicant asserts that Meyer et al. fails to disclose "a distal end comprising an elongate tip having a second substantially uniform diameter." However, the Examiner disagrees. As can be seen in Figure 1, Meyer et al. discloses an elongate tip ending at distal end 14. The Examiner considers the elongate tip having a substantially uniform diameter in that by using the term "substantially" the claim does not require the elongate tip to have the same diameter. The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. In re Nehrenberg, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). Applicant asserts that Eskuri fails to disclose a coating having a taper that approximates the taper of the elongate member. However, the Examiner disagrees. The slope of both the taper of the interior of the coating and the taper of the elongate member are the same because the coating is formed over the taper. Thus, the coating has a taper which approximates the taper of the elongate member. Because the marker as disclosed by Eskuri has a weight, the marker inherently provides localized weight to the flexible tip.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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